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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,146	12/04/2003	Timothy A. Ringeisen	KN P 0146	1356

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KENSEY NASH CORPORATION  
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EXAMINER
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ROGERS, JAMES WILLIAM

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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09/05/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/729,146	<b>Applicant(s)</b> RINGEISEN ET AL.	
	<b>Examiner</b> James W. Rogers, Ph.D.	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07/27/2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 22-26, 28-33, 36-50 and 52-92 is/are pending in the application.
- 4a) Of the above claim(s) 66-92 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-26, 28-33, 36-50, 52-65 and 74-87 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/27/2007 has been entered.

### **Election by Original Presentation**

Newly submitted claims 88-92 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: All previously elected claim sets were drawn to an implantable device and a compressed fibrous matrix. Claims 88-90, which require a second implantable device, were already non elected without traverse by applicants from the response to the election restriction filed 05/16/2006. Methods of fabricating a fibrous member as now claimed in claims 91-92 were also non-elected without traverse by applicants from the response to the election restriction filed 05/16/2006. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 88-92 are

withdrawn from consideration as being directed to a non-elected invention. See  
**37 CFR 1.142(b)** and **MPEP § 821.03**.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-26, 28-33, 38-45, 47-49, 52-53, 61-65, 74-77, 80-81, 84 and 87 are rejected under 35 U.S.C. 102(b) as being anticipated by Stone (US 5,158,574, disclosed previously).

Stone teaches a prosthetic meniscus with one or more types of cross-linked bioabsorbable fibers, which are oriented in phosphate buffered saline solution by compressing with a rotating piston; the meniscus contains pores in which a bioactive agent (adhesion molecule) can be contained. See col 3 line 9-66, col 4 lin 16-33, col 6 lin 40-66, col 8 lin 57-64 and examples. Regarding the product by process limitations within claims 22, 31 and 42, “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Since Stone teaches oriented fibers it reads on applicants claimed invention

drawn to an implantable device or a compressed fibrous matrix. Regarding claims 23 and 24, the limitation that the implantable device contains at least one reinforcing element is met because Stone teaches that the prosthetic can comprise a mesh, See col 4 lin 5-11. Regarding claim 31 Stone clearly teaches that the GAG crosslinkers employed may be concentrated at different areas including points of high stress, typically the distal regions (14 and 16 in Fig 1) and less concentrated at the central region (12 in Fig 1), the distal region is periphery to the central region, therefore the limitation is met. Regarding claims 43-45 the Stone patent teaches that the fibers can be formed in an oriented or random manner, see col 11 lin 18-25. Regarding claim 49 Stone uses phosphates which are well known plasticizers known to those skilled in the art therefore the limitation is met. Regarding claim 74 lubricant was defined by the examiner as a substance (usually a liquid) introduced between two moving surfaces to reduce the **friction** and **wear** between them, therefore the solution used in Stone would meet this limitation.

Claims 22-26,28-30,37-48,52-65,74-84 and 87 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al. (US 2002/0127270, disclosed previously).

Li teaches an oriented crosslinked bipolymeric membrane formed by compressing an aqueous solution containing the fibers and orientating the fibers by a rotating mandrel, the membrane also can contain a bioactive agent. See [0004]-[0005], [0009], [0010], [0011]-[0043], [0056], [0061]. Regarding the product by process limitations within claims 22, 31 and 42, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the

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product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Since Li teaches oriented fibers it reads on applicants claimed invention drawn to an implantable device or a compressed fibrous matrix. Regarding claims 23 and 24, the limitation that the implantable device contains at least one reinforcing element is met because Li teaches that the membrane can contain a mesh, See [0051]. Regarding claim 37 the Li patent clearly states that the biopolymeric fibers possess greater mechanical strength due to their orientation in one direction, allowing them to be sutured thus meeting the limitation that the implantable device is arranged to accept a suture and resist tearing. Regarding claims 41 and 46 Li teaches a method of fabricating multiple layer membrane (meeting multiple plates) the layers are preferably oriented in different directions, thus meeting the limitation in claim 46. See [0005], [0021]-[0042] and [0061] Regarding claims 43-45 the Li patent teaches that by controlling the angle of fiber orientation between the two layers, mechanical properties of the bilayer membrane are defined, thus it is inherent that one skilled in the art would through routine experimentation find the best orientation of the plates whether they are oriented, aligned or randomly orientated towards one another to achieve the desired properties of the film, see [0061]. Regarding claim 74 lubricant was defined by the examiner as a substance (usually a liquid) introduced between two moving surfaces to reduce the

**friction** and **wear** between them, therefore the solution used in Li would meet this limitation.

### ***Response to Arguments***

Applicant's arguments filed 07/27/2007 have been fully considered but they are not persuasive.

Applicants assert that neither the processes of Li nor Stone are different from the claimed method in which the fluid migrates to the side or away from the compression of the fibrous dough. Applicants further state that neither suggests the claimed articles featuring a plurality of plates of aligned fibers.

The relevance of these assertions is unclear. Firstly applicants claimed invention is to an implantable device and a fibrous network, not a method of fabrication. As above since Li and Stone read on applicants claimed invention all the claim limitations rejected above are considered met. Since we are discussing the claimed product we must compare the implants described in the art with applicants claimed invention. The limitations that the implants comprise fibers, which are at least partially aligned plates, is simply not found very limiting by the examiner. Since the cited Stone and Li references describe implantable fibers, which are produced by compressing it is inherent that the fibers must at the very least form some plates of at least some of the fibers when they are compressed. Also at least Li states that the orientation of the fibers is in one direction, thus meeting the limitation of at least partial alignment. Applicants cannot exclude other processes to make polymer implants just because of comments within their remarks/arguments, it must be explicitly excluded from the claims, however the

claims are drawn to a product therefore the method to produce the product is of little relevance as long as the claimed product is met by the prior art.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 22-26,28-33,36-50,52-65 and 74-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (US 5,158,574) in view of Li et al. (US 2002/0127270) and in further view of Haldimann (US 6,428,576 B1, disclosed previously).

Stone is disclosed above. Stone does not disclose a compressed fiber matrix in which the orientation of fibers within each plate is independent of the orientation of fibers within adjacent plates. Stone also does not specifically disclose that the implantable device has any special mechanical properties that would resist tearing from



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a suture. Stone is silent on the use of the membrane as a swellable hemostatic plug but it would be obvious to one skilled in the art at the time of the invention that since collagen is well known to swell when exposed to water (forming gelatin), it would be obvious that such a device could be used as a swellable hemostatic plug. Lastly Stone is silent on the use of plasticizers in the fiber matrix.

Li is disclosed above. Li does disclose a method of fabricating a multiple layer membrane in which the layers are preferably oriented in different directions. Li also discloses that the biopolymeric fibers possess greater mechanical strength due to their orientation in one direction, allowing them to be sutured.

Haldiman is used primarily to show that the use of plasticizers and particulates in implantable bio-polymers was well known to the skilled artisan at the time of the invention. See abstract, col 9 lin 12-28 and example 8. Therefore by combining the Haldiman reference with Stone and Li the claimed elements of an implantable device comprising polymeric fibers and further comprising plasticizers were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Stone discloses all of applicants claimed invention except independent orientation of the fibers in different layers and Stone does not disclose an increase in the tear resistance of the oriented fiber while the Li patent discloses the layers are

preferably oriented in different directions in order to achieve greater mechanical strength which would be resistant to tearing by suture due to its increased mechanical strength. The motivation to combine the above documents would be an oriented fibrous implant comprised of multiple plates that can be oriented at any angle to one another to achieve greater mechanical strength with the benefit of more resilience to tearing from suturing. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

### ***Response to Arguments***

Applicant's arguments filed 07/27/2007 have been fully considered but they are not persuasive.

Applicants assert that Haldiman fails to remedy the deficiencies of Stone and Li in that Haldimann does not disclose or suggest the implants featuring aligned fibers in the form of plates.

The relevance of this assertion is unclear. Haldimann was only used as a secondary reference for its disclosure within that the use of plasticizers and particulates in implantable bio-polymers was well known to the skilled artisan at the time of the invention. Haldiman was not used for a disclosure on implants featuring aligned fibers in the form of plates, clearly from the above rejections and response to arguments Li and Stone meet these limitations.

### **Conclusion**


No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D.

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whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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SUPERVISORY PATENT EXAMINER